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## REDUCTION OF SWELLING IN HEMORRHOIDAL TISSUES

Background of the Invention

This invention relates to a device for reducing the swelling of hemorrhoidal tissues. This invention also relates to an associated method for reducing the swelling of hemorrhoidal tissues.

Hemorrhoids are a common malady which causes substantial pain and suffering to millions of people. The best conventional treatment for this affliction is a soaking of the hemorrhoidal tissues in a hypertonic bath, such as a solution of epsom salts. However, this treatment is not especially convenient for obvious reasons. A need exists for a more convenient and yet effective treatment for hemorrhoids.

Objects of the Invention

An object of the present invention is to provide a device for treating swollen hemorrhoidal tissues.

A related object of the present invention is to provide an associated method for treating swollen hemorrhoidal tissues.

Another, more particular, object of the present invention is to provide such a device for treating hemorrhoids which is reusable.

These and other objects of the present invention will be apparent from the drawings and detailed descriptions herein.

Summary of the Invention

A device for reducing swelling of hemorrhoids comprises, in accordance with the present invention, an essentially rigid rectal insert member and a semipermeable membrane attached to the rectal insert member so that the membrane is in substantial direct contact with hemorrhoidal tissues upon insertion of the rectal insert member into a rectum. A fluidic material is contained in the membrane, the fluidic material being hypertonic with respect to hemorrhoidal tissues and including a non-aqueous molecular substance giving rise to an osmotic pressure tending to draw water into the fluidic material through the membrane. The membrane is permeable to water and impermeable to the molecular substance, whereby water is absorbed from hemorrhoidal tissues upon insertion of the rectal insert member into a rectum.

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According to another feature of the present invention, the device further comprises a component attached to the rectal insert member for removing the rectal insert member from a rectal orifice upon completion of a hemorrhoidal treatment. The removal component may include an elongate tensile element and/or a flange on a proximal end of the rectal insert member.

In a particular embodiment of the invention, the rectal insert member includes a plurality of ribs defining a cage-like structure. The membrane is disposed inside the cage-like structure or, alternatively, outside the cage-like structure of the rectal insert member.

According to a further feature of the present invention, the hemorrhoids treatment device also comprises means for forcing additional hypertonic fluidic material into the membrane. For example, the probe may be connected to a source of pressurized or pressurizable hypertonic fluidic material.

According to an additional feature of the present invention, the hemorrhoids treatment device also comprises means attached to the rectal insert member for automatically ejecting medication in response to absorption of water through the membrane. For example, an inner end of the rectal insert may be provided with a chamber containing the medication, a non-permeable membrane or diaphragm being disposed between that chamber and the fluidic material within the semi-permeable membrane. Upon absorption of water from the hemorrhoidal tissues during use of the device, the medication is forcibly pressed from the storage chamber into the user.

According to a specific feature of the present invention, the fluidic material is an aqueous solution of the non-aqueous molecular substance dissolved in water. The molecular substance may be a salt such as magnesium sulfate (epsom salts) or a sugar or a complex carbohydrate such as amylose. Alternatively, the fluidic material contain gastrograffin or a polymeric hydrogel such as hydroxyethyl methacrylate, glycerol methacrylate, and polyvinylpyrrolidone

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and mixtures thereof.

The semipermeable membrane is preferably soft and pliable and may be made of water-absorbent material.

According to yet another feature of the present invention, the membrane is elastic and defines an outer surface of the rectal insert member. The membrane is positioned along the rectal insert member so that the membrane expands upon a drawing of water from hemorrhoidal tissues through the membrane.

According to yet a further feature of the present invention, the rectal insert member is provided with a closable access means for obtaining access to the membrane to replace the fluidic material.

According to a supplemental feature of the present invention, the rectal insert member is hollow, further comprising an inserter member removably inserted into the rectal insert member for use in pushing the rectal insert member into a rectal orifice.

In a method for treating hemorrhoids in accordance with the present invention, a rectal probe is provided including an essentially rigid member and a stop portion attached to the rigid member, the rectal probe further including a semipermeable membrane attached to the rigid member. In subsequent steps of the method, the rigid member of the rectal probe is inserted through a rectal orifice of a patient and the stop portion of the rectal probe is maintained in engagement with skin tissues of the patient outside of the rectal orifice upon insertion of the rigid member, thereby maintaining the rectal probe in contact with the hemorrhoidal tissues. Water is drawn from the hemorrhoidal tissues of the patient through the semipermeable membrane into the rectal probe while the stop portion of the rectal probe is maintained in engagement with skin tissues of the patient outside of the rectal orifice. The hemorrhoidal tissues are shrunk during and by virtue of the drawing off of the water. The probe is removed from the rectal orifice only upon a substantial shrinkage of the hemorrhoidal tissues.

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The stop portion is an annular flange attached to the rigid member.

Another device for reducing swelling of hemorrhoids comprises, in accordance with the present invention, a rigid body member and a layer of water absorbent material surrounding and attached to the rigid body member. The body member is insertable with the layer through a rectal orifice. A stop element is attached to one end of the body member for maintaining the body member in a patient so that the water absorbent material is contact with the hemorrhoidal tissues. The water absorbent material may be a sponge-like element or a semipermeable membrane.

Pursuant to another feature of the present invention, the body member is hollow and is filled with a fluidic material including a non-aqueous molecular substance giving rise to an osmotic pressure tending to draw water into the fluidic material.

Pursuant to another feature of the present invention, the device further comprises a semipermeable membrane different from the water absorbent material and attached to the body member.

A device for treating hemorrhoidal tissues in accordance with the present invention reduces swelling without the necessity for placing the patient in a bath. Accordingly, a method utilizing the device is convenient. For example, in treating hemorrhoids, the device may be used virtually anywhere. The device may be discarded upon use or re-used, in the event that an access port is provided.

#### Brief Description of the Drawing

Fig. 1 is a side elevational view of a rectal probe in place inside a patient with hemorrhoids, in accordance with the present invention.

Fig. 2 is a schematic cross-sectional view of the rectal orifice in Fig. 1, showing reduction of hemorrhoidal swelling after use of a rectal probe in accordance with the present invention.

Fig. 3 is a schematic cross-sectional view of

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another rectal probe with a hypertonic or hydroscopic solution in accordance with the present invention.

Fig. 4 is a schematic side elevational view of a further rectal probe in accordance with the present invention.

Fig. 5 is a schematic cross-sectional view of a device for reducing the swelling of external organic tissues.

Fig. 6 is a schematic cross-sectional view of a similar device for reducing the swelling of external organic tissues.

Fig. 7 is partially a schematic side elevational view and partially a block diagram of a device for reducing the swelling of internal organic tissues, showing the device in a non-use configuration.

Fig. 8 is a schematic side elevational view of the device of Fig. 7, showing the device in a use configuration.

Fig. 9 is partially a schematic side elevational view and partially a block diagram of a device for reducing the swelling of internal organic tissues, particularly gastritis affected tissues, showing the device in a use configuration inside a stomach.

Fig. 10 is a schematic side elevational view of a device for reducing the swelling of traumatized muscle tissue.

Fig. 11A is a side elevational view of a rectal probe in accordance with the present invention, showing the probe at the onset of a treatment procedure in place inside a patient with hemorrhoids.

Fig. 11B is a view similar to Fig. 11A, showing the probe at a later stage of a treatment procedure in place inside a patient with hemorrhoids.

Fig. 12 is a schematic cross-sectional view of a rectal probe similar to the probe of Fig. 3, showing the probe with an expanded semi-permeable membrane after use of the probe to treat hemorrhoidal tissues.

Fig. 13 is partially a schematic side elevational view and partially a block diagram of a device for treating hemorrhoids, in accordance with the present invention.

Fig. 14A is a schematic cross-sectional view, on a

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reduced scale, of another rectal probe in accordance with the present invention, showing the probe prior to use.

Fig. 14B is a view similar to Fig. 14A, showing the probe after use in treating hemorrhoidal tissues.

Fig. 15A is a schematic cross-sectional view of yet another rectal probe in accordance with the present invention, showing the probe ready for use.

Fig. 15B is a view similar to Fig. 15A, showing the probe after use in treating hemorrhoidal tissues.

Fig. 16 is partially a schematic perspective view and partially a cross-sectional view of yet another rectal probe in accordance with the present invention.

Fig. 17 is a schematic side perspective view of a further rectal probe in accordance with the present invention.

Fig. 18A is a schematic side perspective view of a rigid rectal insert or support member of another hemorrhoids treatment rectal probe in accordance with the present invention.

Fig. 18B is a schematic side perspective view of a flexible bag attachable to the rigid rectal insert or support member of Fig. 18B to form yet another rectal probe for the treatment of hemorrhoids, in accordance with the present invention.

Fig. 19 is a schematic side perspective view of a cage-like ribbed rigid support member for an additional hemorrhoids treatment rectal probe in accordance with the present invention.

Fig. 20 is a schematic side perspective view of a cage-like ribbed rigid support member for yet another hemorrhoids treatment rectal probe in accordance with the present invention.

#### Detailed Description

As illustrated in Fig. 1, a rectal probe 10 is inserted into a rectal orifice R0 afflicted by swollen hemorrhoidal tissues HT. Rectal probe 10 includes a body member 12 and at least one semipermeable membrane 14 disposed along an outer surface or wall of body member 12 so that the

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membrane is held in contact with the swollen hemorrhoidal tissues HT upon insertion of the probe into rectal orifice RO. Rectal probe 10 may be provided at a distal end with an enlarged head 16 serving to maintain the probe in rectal orifice RO during treatment of hemorrhoidal tissues HT. Rectal probe 10 may also be provided at a proximal end with a flange 18 which limits the penetration of the probe and which facilitates retrieval and removal thereof upon completion of a tissue reduction procedure.

Rectal probe 10 contains a hypertonic or hygroscopic fluid which includes a non-aqueous substance which serves to generate an osmotic pressure into the probe through membrane 14. The hypertonic fluid should be biocompatible and may take the form of ethanol. However, the hypertonic fluid is preferably an aqueous solution of a solute dissolved in water. In that event, the solute is the non-aqueous substance which gives rise to the osmotic pressure of the hypertonic solution. The solute may be magnesium sulfate (Epsom salts) or sugar.

Fig. 2 illustrates reduction of the swelling of hemorrhoidal tissues HT after use of rectal probe 10.

As depicted in Fig. 3, a rectal probe 20 comprises a body member 22 provided along a central portion with an array of perforations 24. Disposed along an outer surface 26 of body member 22 is a semipermeable membrane 28. Body member 22 defines a central chamber 30 which carries a hypertonic or hygroscopic solution 32. The solution only partially fills chamber 30, in order to allow for the absorption of water during a treatment operation.

Semipermeable membranes 14 and 28, as well as the other semipermeable membranes disclosed herein for contact with sensitive internal body tissues, are preferably soft, pliable sheets which minimize irritation of the organic tissues during use of the hypertonic device. In addition, those membranes are preferably made of a water-absorbent substance, which becomes permeated with water (but not solute). In the event that probe device 10 or 20 or other rectal probes r

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suppositories described herein are marketed with the hypertonic fluid or solution, an external protective sheath (not shown) may be provided for isolating membrane 14 or 28 from the environment and vice versa. The sheath is removed prior to use of the probe device.

As illustrated in Fig. 4, another rectal probe 34 comprises a body member 36 provided along a central portion with a plurality of windows or apertures 38 each covered by a semipermeable membrane 40. Membrane 40 may be a unitary web, as indicated by dot-dash lines 42 and 44. Alternatively, windows 38 may be provided with respective semipermeable covers separate from each other. In any case, membrane 40 forms an outer wall or surface of body member 36 and engages swollen hemorrhoidal tissues (e.g., HT in Figs. 1 and 2) upon disposition of rectal probe 34 in a treatment procedure.

Rectal probe 34 may in some cases take the form of a rectal suppository. In that case the probe remains in the rectal orifice until it is flushed out during a bowel movement. Alternatively, the probe may be provided with a string or other tensile element 45 for facilitating removal of the probe. A similar string or tensile element may be provided on other hypertonic rectal probes disclosed herein for facilitating removal of the probes from a rectal orifice upon completion of hemorrhoid treatment.

Probe 10 (Fig. 1) may also be used as a suppository. In that event, flange 18 is omitted and membrane 14 may extend around the entire body of the probe.

Figs. 5 and 6 show respective devices 46 and 48 designed for reducing the swelling of external organic tissues OT. Device 46 comprises a rigid or semirigid body or casing member 50 containing a hypertonic solution 52 and provided along one wall 54 with an array of perforations 56. Disposed along an outer side of wall 54 is a semipermeable membrane 58. Device 46 is placed on swollen external organic tissues OT so that membrane 58 is in contact with those tissues.

Device 48 in Fig. 6 will be more appropriate for many uses. Device 48 comprises a body member or casing 60

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made of a flexible, elastic material filled with a hypertonic or hydroscopic solution 62. A wall portion 64 of body member 60 is formed by a semipermeable membrane. Because body member 64 is flexible, it may be shaped to conform to the contour of swollen external tissues.

As illustrated in Fig. 7, a device for reducing the swelling of internal organic tissues, comprises a balloon 66 attached to the distal end of a tube 68 in turn connected at a proximal end to a source 70 of a hypertonic solution. Tube 68 is preferably made of a semirigid material, whereby tube 68 maintains its form but will flex to some extent under compressive pressure. Balloon 66 is made at least in part of a semipermeable membrane 71.

Fig. 8 shows balloon 66 and tube 68 inserted into an essentially tubular organ TO such as a urethra, an intestine or an esophagus. Balloon 66 has been juxtaposed to or aligned with a region of internal swelling RIS such as that occasioned by an anastomosis operation. Subsequently to the juxtaposition of balloon 66 and swelling RIS, a hypertonic or hydroscopic solution 72 has been fed or injected into balloon 66. To that end source 70 may take the form of a pump or a syringe 70, as illustrated in Fig. 8. Upon the elapse of a sufficient time to permit the reduction of swelling, source 70 is operated to withdraw hypertonic solution 72 from balloon 66 via tube 68. Balloon 66 and tube 68 are then extracted from the patient and discarded.

As illustrated in Fig. 9, another balloon 74 and tube 76 are inserted through a patient's esophagus PE into the stomach ST. Balloon 74 is made at least in part of a semipermeable membrane. Balloon 74 is inflated or expanded with a hypertonic or hydroscopic solution (not illustrated) which is fed or supplied from a reservoir 78 via a pump 80 and a valve 82 connected to tube 76. Subsequently to the inflation of balloon 74, tube 76 may be placed in tension to maintain the balloon in contact with swollen tissues in a gastritic region about the gastricesophageal junction GEJ.

It is to be noted that the devices of Figs. 8 and 9

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may be provided with pressure sensitive components (not shown) connected to tubes 68 and 76 for maintaining the hypertonic solution in balloons 66 and 74 at a substantially constant pressure or for automatically feeding increased amounts of hypertonic solution to balloons 66 and 74 as the swelling of the tissues is reduced. In that way, balloons 66 and 74 will maintain contact with the swollen tissues as the swelling subsides, thereby accelerating the treatment.

As illustrated in Fig. 10, a device for treating swollen muscle tissues, such as in a leg or thigh LG, comprises an elongate rod 84 carrying a hypertonic or hydroscopic solution (not illustrated) and provided along an external wall with a semipermeable membrane 86. Rod 84 is inserted through an incision SI made in the skin surface overlying or juxtaposed to the swollen muscle tissues of leg or thigh LG.

As illustrated in Fig. 11A, a rectal probe 90 is inserted into a rectal orifice RO' afflicted by swollen hemorrhoidal tissues HT'. Rectal probe 90 includes a body or frame member 92 and at least one semipermeable membrane 94 surrounding the body member 92 so as to define an at least partially cylindrical outer surface or wall thereof. Body member 92 serves to support membrane 94 in an upright, elongated configuration and to enable or facilitate insertion of membrane 94 into rectal orifice RO' so that the membrane is held in contact with the swollen hemorrhoidal tissues HT' upon insertion of the probe into rectal orifice RO'. Body member 92 may be provided at a distal end with an enlarged head 96 serving to maintain the probe in rectal orifice RO' during treatment of hemorrhoidal tissues HT'. Body member 92 may also be provided at a proximal end with a flange 98 which limits the penetration of the probe and which facilitates retrieval and removal thereof upon completion of a tissue reduction procedure.

Membrane 94 is elastic and accordingly expands upon diffusion of water molecules through the membrane from hemorrhoidal tissues HT' after the probe has been inserted into orifice RO' during a treatment procedure, as illustrated

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in Fig. 11B. The expansion of membrane 94 and, accordingly, of probe 90 serves in part to maintain membrane 94 in substantial direct contact with swollen hemorrhoidal tissues HT' during the treatment, thereby enhancing the efficacy of the procedure.

Membrane 94 may be connected to body member 92 along head 96 and flange 98, thereby permitting expansion or inflation of the membrane about a central shaft 99 of body member 92.

As depicted in Fig. 12, a rectal probe 100 comprises a body member 102 provided along a central portion with an array of perforations 104. Disposed along an outer surface 106 of body member 102 is an elastic semipermeable membrane 108 connected to body member 102 at a base end 110 and a head 112 thereof. A cylindrical central portion 114 of membrane 108 is unattached to body member 102. Body member 102 defines a central chamber 116 which carries a hypertonic solution 118. Upon use of probe 100 in the treatment of hemorrhoids, membrane 108 and particularly central portion 114 thereof expands upon diffusion of water through the membrane from hemorrhoidal tissues.

As additionally depicted in Fig. 12, base 110 of probe 100 is provided with an access port 120 covered with a removable plug or door 122. Plug or door 122 may be provided with a knob 124 for facilitating removal of the plug upon the termination of a hemorrhoidal treatment. Upon extraction of probe 100 from a rectal orifice and upon removal of plug 122 from port 120, diluted hypertonic solution 118 is poured off. Probe 100 may then be refilled with fresh hypertonic solution in anticipation of a subsequent reuse of the device. Of course, membrane 108 collapses upon removal of plug 122 and again conforms to the outer surface 106.

Fig. 12 illustrates plug 122 as attachable in a force-lock fit to body member 102. However, other equivalent attachment techniques may be used, for example, a snap-lock fit (ridge and groove) or a screw-type connection.

Probes 10, 20, 34 and 90 may similarly be provided

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with closable access ports for enabling refilling and reuse of the probes.

Fig. 13 shows a probe 130 wherein removal of diluted hypertonic or hydroscopic solution may be effectuated via a valve mechanism 132 connected via a hose 134 to the probe. Valve mechanism 132 is also connected to a pressurized or pressurizable source 136 of hypertonic solution. Source 136 may take the form of a collapsible bladder or pouch which is manually collapsible via a squeezing action. Valve mechanism 132 is disposed between source 136 and probe 130 to control the direction of fluid flow at different stages during a hemorrhoidal treatment.

Probe 130 includes an expandable or deformable semi-permeable membrane 138 attached to an elongate support 140 having an enlarged head portion 142 at a distal end and a flange 144 at a proximal end.

During insertion or placement of probe 130 in a rectal orifice (not shown), membrane 138 is in a relatively collapsed or deflated configuration, as illustrated in Fig. 13, owing to a low fluid pressure. The relatively small size of probe 130 facilitates insertion of the probe and minimizes discomfort to the user. Upon insertion of probe 130, valve mechanism 132 is actuated to enable the transfer of hypertonic fluid from source 136 to probe 130. Valve mechanism 132 and/or source 136 is controlled by the user to maximize the pressure of the hypertonic solution inside probe 130, thereby maintaining maximal direct contact between hemorrhoidal tissues and semi-permeable membrane 138, without causing undue pain to the user. The user is thus able to balance the rate of water absorption against the pressure on the hemorrhoidal tissues by probe 130.

Upon absorption of water from the user's hemorrhoidal tissues, valve mechanism 132 may be actuated to drain diluted hypertonic solution from probe 130 and to refill the probe while the probe remains inserted in the user's rectal orifice. With that procedure, the effectiveness of hemorrhoidal treatment is enhanced inasmuch as a renewed high

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concentration of hypertonic solution draws water at a higher rate from the hemorrhoidal tissues. Upon termination of the treatment, valve mechanism 132 may be used to empty probe 130 of the diluted hypertonic solution prior to removal of probe 130 from the user's rectal orifice, thereby facilitating removal and reducing any pain which would otherwise be experienced during the removal process.

Valve mechanism 132 may take any suitable form. In a simple embodiment, hose 134 is bifurcated, with one branch extending to source 136 and another branch serving as an outlet, each branch being provided with a releasable clamp.

As shown in Fig. 14A, a rectal probe 150 comprises a body member 152 provided along a central portion with an array of perforations 154. Disposed along an outer surface 156 of body member 152 is a semipermeable membrane 158 connected to body member 152. Body member 152 defines a central chamber 160 which carries a hypertonic or hygroscopic solution 162. A base 164 of probe 150 is provided with an elastic impermeable membrane 166. Upon insertion of probe 150 into a user's rectum and consequent absorption of hemorrhoidal water, membrane 166 expands, as illustrated in Fig. 14B, to provide a reservoir 167 for the absorbed water.

Any probe or removable suppository for the treatment of hemorrhoidal tissues, as described herein, may be provided with a string 45 (Fig. 4) for facilitating removal of the device upon completion of treatment. In addition, the outer surface of the probe or suppository may be provided with a film of a local anesthetic or other medication prior to insertion, thereby providing immediate temporary relief.

As depicted in Fig. 15A, another rectal probe 170 comprises a body member 172 provided along a central portion with an array of perforations 174. Disposed along an outer surface 176 of body member 172 is a semipermeable membrane 178 connected to body member 172. Body member 172 defines a central chamber 180 which carries a hypertonic or hygroscopic solution 182. Probe 170 is hollow and is provided along an inner surface with an elastic impermeable membrane 186.

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As further depicted in Fig. 15A, prior to use of the probe 170, an elongate inserter portion 188 of an applicator 190 is disposed inside membrane 186. Applicator 190 is used to insert probe 170 inside a user's rectal orifice. To that end applicator 190 is provided at a proximal end with a handle portion 192.

Upon insertion of probe 170 into a user's rectum, inserter portion 188 of applicator 190 is removed from the probe. Subsequent absorption of hemorrhoidal water causes membrane 186 to expand or deform inwardly, as illustrated in Fig. 15B, whereby chamber 180 increases in volume to provide a reservoir for the absorbed water. A string (not illustrated) may be attached to probe 170 to facilitate the removal thereof from a rectal orifice upon completion of the hemorrhoid treatment.

As illustrated in Fig. 16, another rectal probe or suppository for the treatment of hemorrhoids includes an elongate, relatively rigid body member 194 provided at one end with a stop in the form of a flange 196. A soft and pliable cylindrical or conical sponge 198 is attached to body member 194. Sponge 198 serves to absorb water, particularly including interstitial water, from swollen hemorrhoidal tissues. Body member 194 may be hollow and filled with a hypertonic solution (not shown) as described herein. A semipermeable membrane (not separately designated) may surround body member 194 as described herein. Sponge 198 is in that event attached to the membrane.

In a variation of the embodiment of Fig. 16, sponge 198 is detachably connected to rigid body member 194. Body member 194 is used as an inserter to position sponge 198 in a rectal orifice or canal and is withdrawn after placement of the sponge. Sponge 198 may be provided with a preformed channel or recess (not designated) receiving the inserter 194.

As shown in Fig. 17, yet another rectal probe for the treatment of hemorrhoids comprises an elongate rigid support or insert member 202 formed at an inner or distal end with an enlarged head portion 204 and attached at an outer or

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proximal end to a flange or stopper element 206. A flexible semi-permeable membrane 208 is connected about a base 210 to flange 206 and contains a hypertonic fluidic material for drawing water through the membrane from hemorrhoidal tissues in contact with the membrane.

Figs. 18A and 18B show cooperating parts of a rectal probe for the treatment of hemorrhoids. An elongate rigid support or insert member 212 shown in Fig. 18A is formed at an inner or distal end with an enlarged head portion 214 and is fastened at an outer or proximal end to a flange or stopper element 216. The support or insert member 212 of Fig. 18A is slid into a channel 218 in a bag member 220 formed along an outer wall with a flexible semipermeable membrane 222. Membrane 222 is connected at a lower or proximal end to a ring 224 in turn formed with an inwardly facing groove 226 for receiving an edge of flange 216 (Fig. 18A) in a snap-lock fit upon an insertion of support or insert member 212 into channel 218. Head portion 214 of rectal support member 212 is snapped into an enlarged end portion 228 of channel 218. Head portion 214 and end portion 228, as well as groove 226 and flange 216, serve to temporarily hold the parts of Figs. 18A and Fig. 18B to one another during use. Subsequently, bag member 220 may be separated from rectal insert member 212 and discarded. Another bag member may be attached to rectal insert member 212 for a subsequent treatment.

As depicted in Fig. 19, a rigid rectal probe insert member 230 comprises a plurality of longitudinally extending ribs 232 connected to each other at an inner or distal end 234 and to a base or flange member 236 at an outer or proximal end. A cage-like support structure is formed by ribs 232 and a plurality of longitudinally spaced annular ribs 238. A semipermeable membrane (not illustrated) containing a hypertonic fluidic material may be disposed either inside or outside the cage-like support structure of insert member 230.

Fig. 20 illustrates another rigid rectal probe insert member 240 comprising a plurality of longitudinally extending ribs 242 connected to a substantially cone-shaped

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housing element 244 at an inner or distal end and to a base or flange member 246 at an outer or proximal end. Ribs 242, together with a plurality of longitudinally spaced annular ribs 248, define a cage-like structure. A semipermeable membrane (not illustrated) containing a hypertonic fluidic material may be disposed either inside or outside the cage-like support structure of insert member 240. Housing element 244 defines a chamber (not designated) containing a fluidic medication which is squeezed out of housing 244 through an aperture 249 by osmotically enhanced pressure exerted via a membrane or diaphragm 250. To that end, diaphragm 250 is more flexible or bendable than the semipermeable membrane (not shown) disposed along ribs 242 and 248.

All the hemorrhoidal treatment probes described herein contain, or may be made to contain, a biocompatible fluidic material which is hypertonic with respect to hemorrhoidal tissues and includes a non-aqueous molecular substance giving rise to an osmotic pressure tending to draw water into the fluidic material through the membrane. The hypertonic or hygroscopic fluidic material may include water also, as in an aqueous solution. The hypertonic fluid may be ethanol or an aqueous solution of a solute dissolved in water. The solute (e.g., magnesium sulfate or sugar) is the non-aqueous molecular substance which cannot pass through the semipermeable membrane and which gives rise to the osmotic pressure of the hypertonic solution.

The fluidic material may contain gastrograffin or a polymeric hydrogel such as hydroxyethyl methacrylate, glycerol methacrylate, and polyvinylpyrrolidone and mixtures thereof. A layer of polymeric hydrogel may be disposed in a hardened form on the surface of a rectal probe in accordance with the present invention in order to facilitate the extraction of water from hemorrhoidal tissues. One skilled in the polymer arts will know to add additional monomers to a polymerizing mixture in order to give rise to cross-linking for purposes of rigidifying the polymeric material in the outer layer. The hydrogel inside the semipermeable membrane may also be

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solidified for ease of transport and insertion during use.

Although the invention has been described in terms of particular embodiments and applications, one of ordinary skill in the art, in light of this teaching, can generate additional embodiments and modifications without departing from the spirit of or exceeding the scope of the claimed invention. Accordingly, it is to be understood that the drawings and descriptions herein are proffered by way of example to facilitate comprehension of the invention and should not be construed to limit the scope thereof.

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## CLAIMS:

1. A device for reducing swelling of hemorrhoids, comprising:

an essentially rigid rectal insert member;  
a semipermeable membrane attached to said rectal insert member so that said membrane is in substantial direct contact with hemorrhoidal tissues upon insertion of said rectal insert member into a rectum; and  
a fluidic material contained in said membrane, said fluidic material being hypertonic with respect to hemorrhoidal tissues, said fluidic material including a non-aqueous molecular substance giving rise to an osmotic pressure tending to draw water into said fluidic material through said membrane, said membrane being permeable to water and impermeable to said molecular substance, whereby water is absorbed from hemorrhoidal tissues upon insertion of said rectal insert member into a rectum.

2. The device defined in claim 1, further comprising means attached to said rectal insert member for removing said rectal insert member from a rectal orifice upon completion of a hemorrhoidal treatment.

3. The device defined in claim 2 wherein said means for removing includes an elongate tensile element.

4. The device defined in claim 2 wherein said means for removing includes a flange on a proximal end of said rectal insert member.

5. The device defined in claim 1 wherein said rectal insert member includes a plurality of ribs defining a cage-like structure.

6. The device defined in claim 5 wherein said membrane is disposed inside said cage-like structure.

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7. The device defined in claim 5 wherein said membrane is disposed outside said cage-like structure.

8. The device defined in claim 1, further comprising means for forcing additional hypertonic fluidic material into said membrane.

9. The method defined in claim 8 wherein said probe is connected to a source of pressurized or pressurizable hypertonic fluidic material.

10. The device defined in claim 1, further comprising means attached to said rectal insert member for automatically ejecting medication in response to absorption of water through said membrane.

11. The device defined in claim 1 wherein said fluidic material is an aqueous solution of said non-aqueous molecular substance dissolved in water.

12. The device defined in claim 1 wherein said fluidic material includes gastrograffin.

13. The device defined in claim 1 wherein said fluidic material includes a polymeric hydrogel.

14. The device defined in claim 1 wherein said membrane is soft and pliable.

15. The device defined in claim 1 wherein said membrane is made of water-absorbent material.

16. The device defined in claim 1 wherein said rectal insert member is substantially surrounded by said membrane.

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17. The device defined in claim 1 wherein said membrane is elastic and defines an outer surface of said rectal insert member, said membrane being positioned along said rectal insert member so that said membrane expands upon a drawing of water from hemorrhoidal tissues through said membrane.

18. The device defined in claim 1 wherein said rectal insert member is provided with a closable access means for obtaining access to said membrane to replace said fluidic material.

19. The device defined in claim 1 wherein said rectal insert member is hollow, further comprising an inserter member removably inserted into said rectal insert member for use in pushing said rectal insert member into a rectal orifice.

20. A method for treating hemorrhoids, comprising the steps of:

providing a rectal probe including an essentially rigid member and a stop portion attached to said rigid member, said rectal probe further including a semipermeable membrane attached to said rigid member;

inserting said rigid member of said rectal probe through a rectal orifice of a patient;

upon completion of said step of inserting, maintaining said stop portion of said rectal probe in engagement with skin tissues of the patient outside of the rectal orifice, thereby maintaining said rectal probe in contact with the hemorrhoidal tissues;

during said step of maintaining, drawing water from the hemorrhoidal tissues of the patient through said semipermeable membrane into said rectal probe;

shrinking the hemorrhoidal tissues during and by virtue of said step of drawing; and

only upon a substantial shrinkage of said hemorrhoidal tissues, removing said probe from said rectal

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orifice.

21. The method defined in claim 20 wherein said stop portion is an annular flange attached to said rigid member.

22. The method defined in claim 20 wherein said semipermeable membrane is disposed outside of said rigid member.

23. The method defined in claim 20 wherein said semipermeable membrane is disposed inside said rigid member.

24. The method defined in claim 20 wherein said semipermeable membrane is attached directly to said rigid member.

25. The method defined in claim 20 wherein said probe contains a water-absorbent fluidic material disposed in said rigid member, said fluidic material being hypertonic with respect to hemorrhoidal tissues, said fluidic material including a non-aqueous molecular substance giving rise to an osmotic pressure tending to draw water into said fluidic material.

26. The method defined in claim 20 wherein said membrane forms an outer surface or wall of said probe, further comprising the step of expanding at least a portion of said membrane during said step of drawing to maintain said membrane in contact with shrinking hemorrhoidal tissues.

27. A device for reducing swelling of hemorrhoids, comprising:

- a rigid body member;
- a layer of water absorbent material surrounding and attached to said rigid body member, said body member being insertable with said layer through a rectal orifice; and
- a stop element attached to one end of said body mem-

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ber, for maintaining said body member in a patient so that said water absorbent material is contact with the hemorrhoidal tissues.

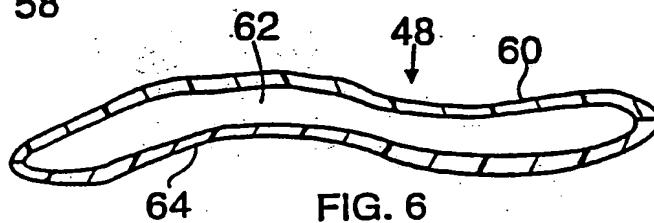
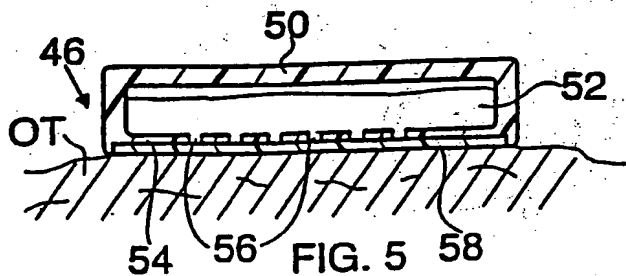
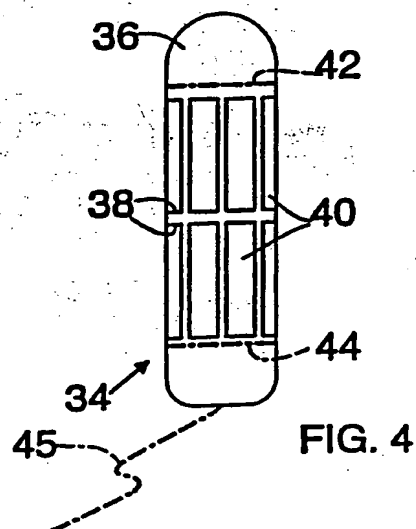
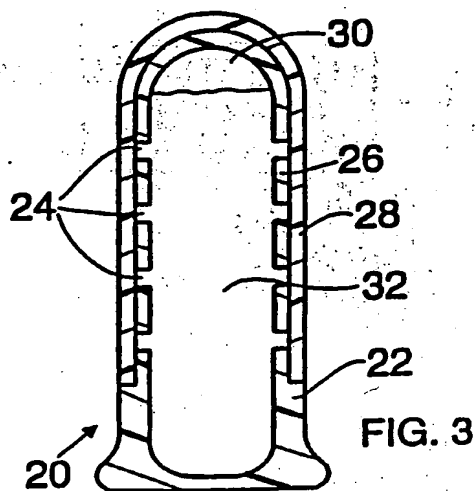
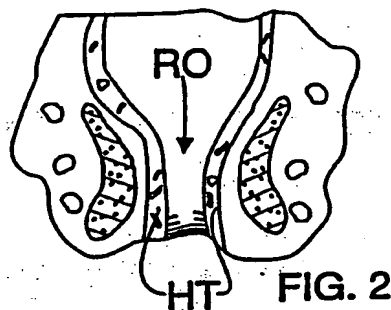
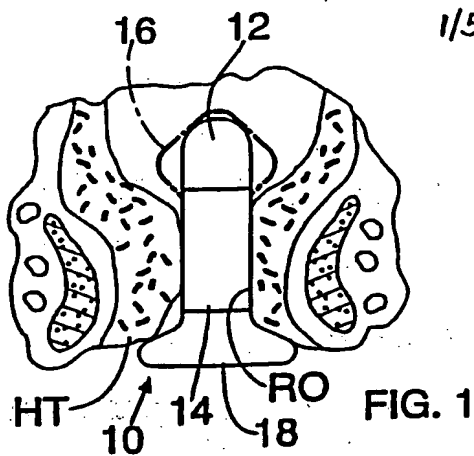
28. The device defined in claim 27 wherein said body member is hollow and is filled with a fluidic material including a non-aqueous molecular substance giving rise to an osmotic pressure tending to draw water into said fluidic material.

29. The device defined in claim 28, further comprising a semipermeable membrane different from said water absorbent material and attached to said body member.

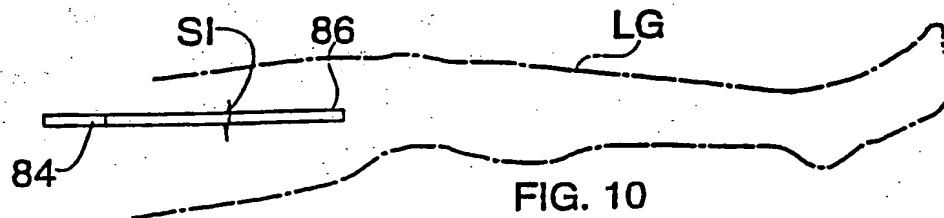
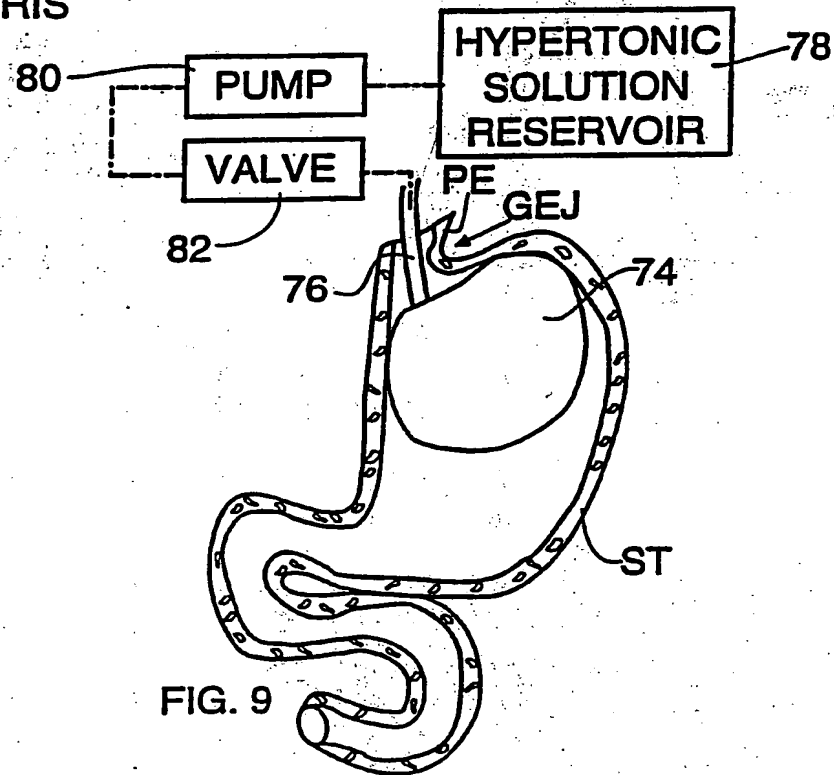
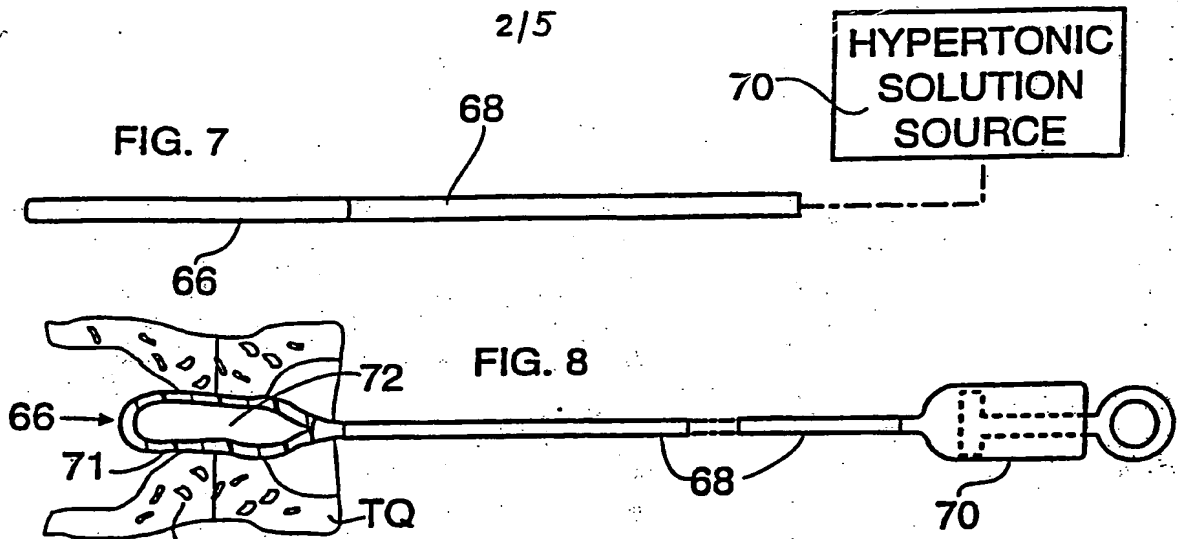
30. The device defined in claim 27 wherein said water absorbent material is a sponge-like element.

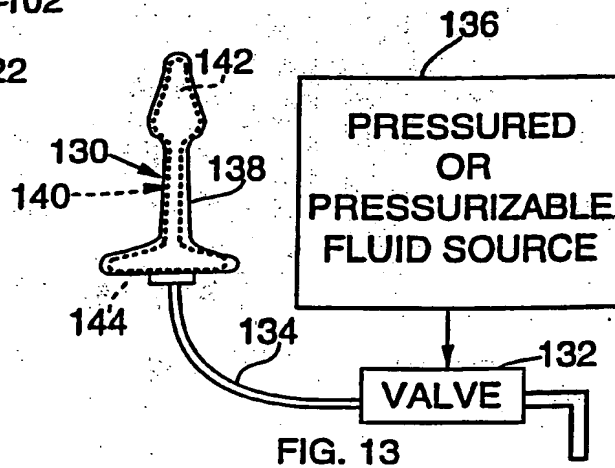
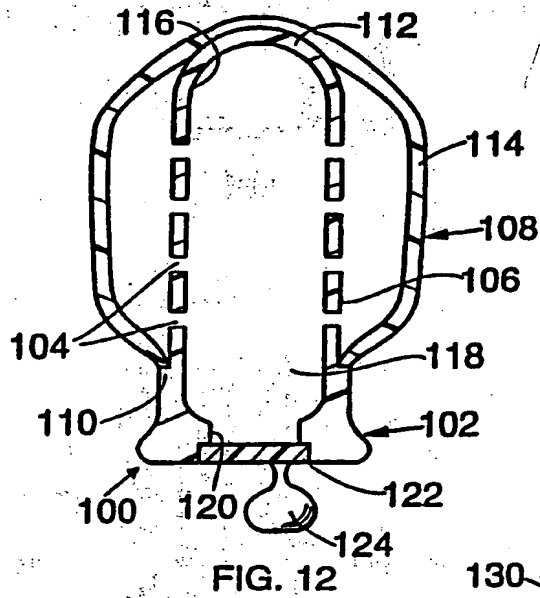
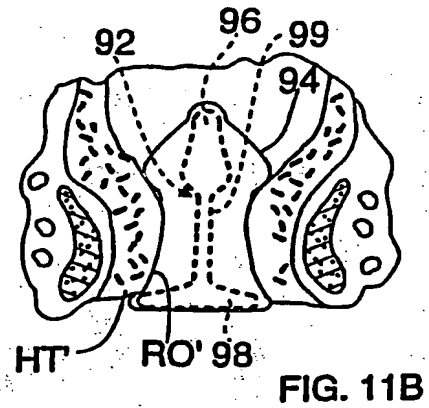
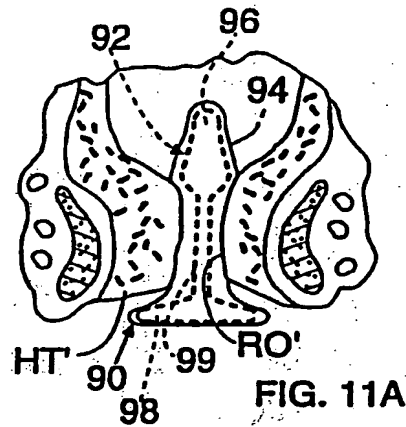
31. The device defined in claim 27 wherein said water absorbent material is a semipermeable membrane.

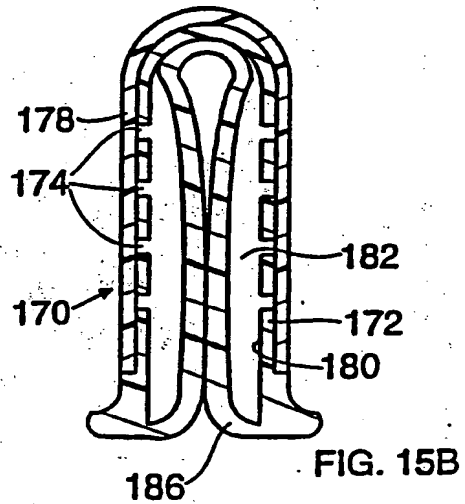
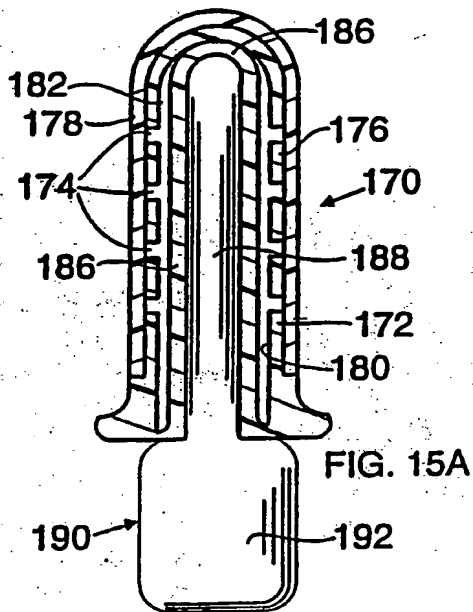
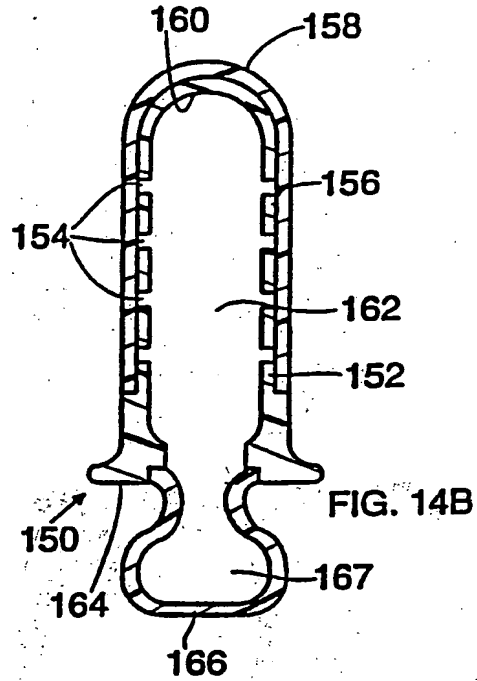
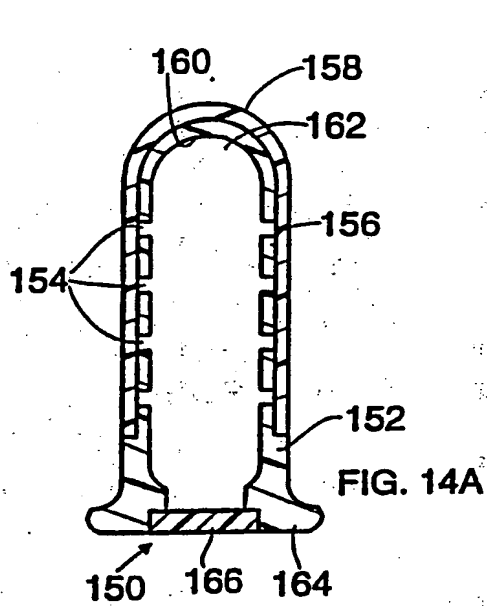
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5/5

FIG. 16

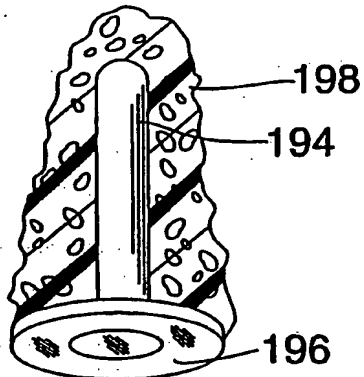


FIG. 17

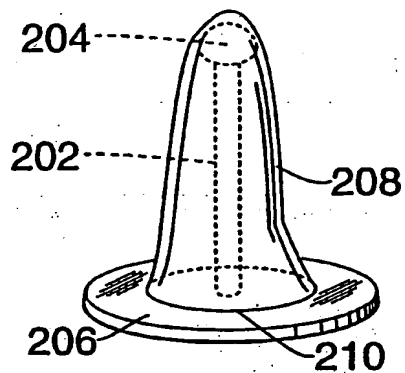


FIG. 18A

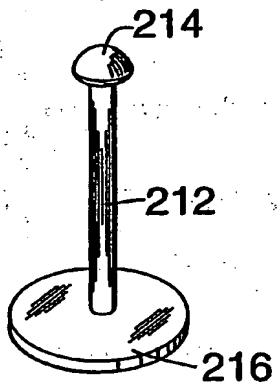
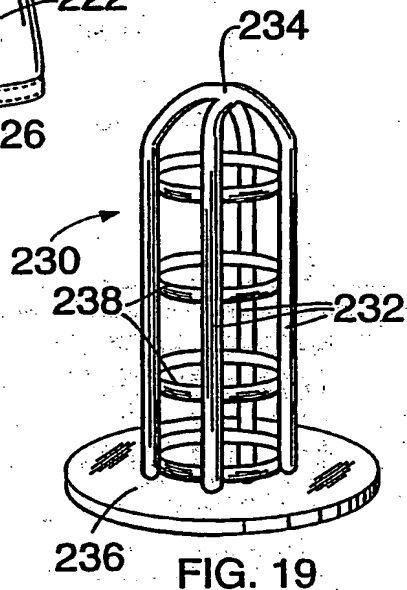
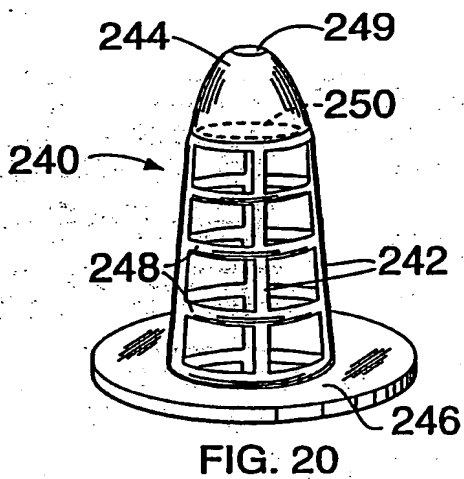
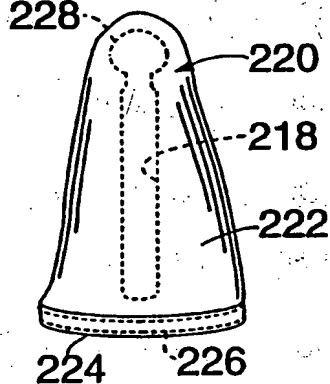


FIG. 18B



SUBSTITUTE SHEET

## INTERNATIONAL SEARCH REPORT

PCT/US93/01856

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(5) : A61M 31/00  
 US CL : 604/11,93,286

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/11,93,286 604/27,285,288,327,328,891.1,891.2

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
 Please See Extra Sheet.

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US,A, 3,760,804 (Higuchi et al.) 25 September 1973 See figure 1; col. 7, lines 25-32; col. 9, lines 32-35.	1,11,14,15 18 2,3
Y	US,A, 2,017,334 (Ackerman) 15 October 1935 See figures 1 and 3.	2,4,20,21,22 24,25,26
Y	US,A, 1,537,992 (Gearon) 19 May 1925 See figures 1-3.	2,3
A	US,A, 3,760,805 (Higuchi) 25 September 1973 See figure 1, Abstract.	1-31
A	US,A, 4,243,652 (Francis) 06 January 1981 See col. 1, lines 36-42.	12

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* "A" document defining the general state of the art which is not considered to be part of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
* "E" earlier document published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
* "L" document which may throw doubt on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
* "O" document referring to an oral disclosure, use, exhibition or other means	"A" document member of the same patent family
* "P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

01 JUNE 1993

Date of mailing of the international search report

22 JUL 1993

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En MARY BETH JONES *Mary Beth Jones*

Telephone No. (703) 308-0855

Form PCT/ISA/210 (second sheet)(July 1992)\*

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US93/01856

## B. FIELDS SEARCHED

Electronic data bases consulted (Name of data base and where practicable terms used):

U.S. Automated Patent System (APS)

OSMO?

Gastrograffin

Hydrogel

Hemorrhoid?